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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,785	08/10/2005	Yoshiaki Miyata	265913US0PCT	8700

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
06/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/524,785	MIYATA ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 02/16/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying this application by its Serial Number and filing date is required. See MPEP 602.01 and 602.02. The oath or declaration is defective because:

It is incomplete because it does not identify the mailing address of any inventor.

No claims have been cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as of the date of this Office action. One Information Disclosure Statement (1 IDS) filed February 16, 2005 has been received with all cited references and made of record.

Claims **1-11** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-11** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the administration of hyaluronic acid in the presence of a buffer, does not reasonably provide enablement for making or using any "hyaluronic acid ester derivative." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The instant claims apply only to compositions comprising a "hyaluronic acid ester derivative," a generic class of substances not further defined in the claims or administered in any specific example disclosed herein. The breadth of the claims is

excessively broad in part as a consequence of the presence of the noted generic term and the indefinite scope thereof.

B. The nature of the invention: The invention is directed to a two part composition wherein one part comprises a "hyaluronic acid ester derivative," and the other part comprises a buffer to be mixed with the first part prior to administration, apparently for the purpose of minimizing discomfort caused during the administration of hyaluronic acid compounds to the joint tissue of a host in need thereof.

C. The state of the prior art: The prior art teaches that hyaluronic acid is an oligo- or poly-saccharide commonly administered to the joints of a host in need thereof (PTO-892 ref. **R**). However, the prior art does not teach or disclose the administration of a "hyaluronic acid ester derivative" for the same purpose.

D. The level of one of ordinary skill: The ordinary practitioner is highly skilled in part of the instant art in view of the well known in the art application of hyaluronic acid compounds to the treatment of disorders of the mammalian joint. However, the prior art does not teach or disclose the administration of a "hyaluronic acid ester derivative" for the same purpose, and therefore the level skill of the ordinary practitioner is probably very low.

E. The level of predictability in the art: A portion of the instant art is highly predictable because the administration of hyaluronic acid to joints is well known in the art. However, the prior art does not teach or disclose the administration of a "hyaluronic acid ester derivative" for the same purpose, and therefore the predictability is probably very low.

F. The amount of direction provided by the inventor: The instant disclosure examples are limited to the administration of hyaluronic acid compounds and does not teach any examples wherein a "hyaluronic acid ester derivative" has been tested.

G. The existence of working examples; The working examples provided are limited to the administration of hyaluronic acid compounds, and does not include administration of any "hyaluronic acid ester derivatives."

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the examples have failed to

provide any guidance relevant to the administration of the active ingredients generically defined by the term "hyaluronic acid ester derivative."

Claims **1-11** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note to applicant: In view of the claims formally not under consideration because of multiple dependence (see 4th paragraph rejection below) and the need to provide a complete Office action, examiner has elected to provide rejections for all of the claims as appropriate in order to assist applicant in determining the best way to proceed.

Claims **1-10** appear to be directed to -- A pharmaceutical composition --. If so, Examiner suggests amendments to conform to a typical format for this kind of claim: -- A pharmaceutical composition comprising {active ingredient(s)} in combination with a pharmaceutically acceptable carrier-- .

In claim **1** the term "characterized in that" is incorrect in a US patent claim because the noted term is not a judicially recognized transitional term. Applicant is respectfully requested to substitute alternative terminology. Examiner suggests that the term "comprises" or the like would be appropriate and that all subsequent claims need to be amended as appropriate to conform to this change.

In claim **1** the term "hyaluronic acid ester derivative" is incomplete because the included term "ester derivative" has not been defined further to indicate the particular "ester derivatives" intended to be included within the metes and bounds of the instant claims. See also claims **2 and 5-7** wherein the same term is presented without further definition.

In claim **3** the term "self-crosslinking hyaluronic acid" is subgeneric but still does not provide sufficient detail to permit determination of the metes and bounds of the claimed subject matter. Applicant is respectfully requested to define specific compounds within the instant claims.

In claim **4** at line 6, the term "hyaluronic acid" lacks proper antecedent basis in claim **1** wherein only "ester derivatives" of "hyaluronic acid" are permitted.

In claim **5** the term "further contains a medicine or a pharmaceutically acceptable lubricant" both lacks proper specific antecedent basis in claim **1** and is indefinite because it fails to define what particular additional medicinal substances or lubricants have been added to the composition defined in claims **1-4**. See also claims **6-8** for reoccurrence of the same problem.

In claim **9** the term "phospholipid" is subgeneric but still does not provide sufficient detail to permit determination of the metes and bounds of the claimed subject matter. Applicant is respectfully requested to define specific compounds within the instant claims.

In claim **10** the term "packed in a syringe separately from each other" suggest a physical limitations in the method of administration that has not been described clearly in the claim, thereby rendering the claim incomplete.

In claim **11** the term "for administration" at the end of the claim suggests that applicant was trying to say -- to host in need thereof --. Examiner respectfully suggests the replacement of the quoted term in order to conform to typical US claim language norms in medical methods of treatment claims.

Claims **4-11** are objected to under 35 C.F.R. §1.75(c), as being in improper dependent form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP §608.01(n). Accordingly, claims **4-11** have not been further treated on the merits.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-11** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **O'Neil et al.** (PTO-892 ref. **R**) in view of **Swinyard et al.** (PTO-892 ref. **S**).

The instant claims are directed to pharmaceutical compositions comprising hyaluronic acid and/or a "hyaluronic acid ester derivative" and the administration of an effective amount thereof into the joint of a host in need of treatment for arthropathy.

O'Neil et al. discloses hyaluronic acid and the administration thereof into the joint of a mammalian host in need of treatment of a joint disorder effectively treated thereby.

O'Neil et al. does not expressly disclose the admixture of a buffer to hyaluronic acid prior to administration to a joint.

Swinyard et al. discloses a substantial array of different substances known to be useful in the preparation of pharmaceutical compositions including phosphate salts typically included in such compositions as buffers.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the disclosure of **O-Neil et al.** with that of **Swinyard et al.** as a part of the process of routine experimentation to optimize a method of treatment disclosed in the prior art (**O'Neil et al.**).

One having ordinary skill in the art would have been motivated to combine these references because it is notoriously well known to the ordinary practitioner that the employment of "Pharmaceutical Necessities" is an essential part of the optimization of prior art processes and products during the process of routine experimentation.

Therefore, the instant claimed pharmaceutical composition comprising hyaluronic acid and/or "hyaluronic acid ester derivatives" and the administration thereof to treat a joint disorder (arthropathy) would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

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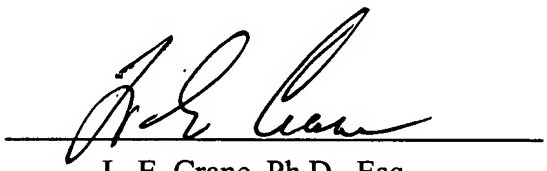

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